510(k) Summary

AS REQUIRED BY 21 CFR 807.92(c)

JAN 20 2011

The Assigned 510(k) number is K102203

Date of Summary: August 3rd, 2010

Common Name: Drugs of Abuse Screening Tests

Classification Name: Immunoassay for the detection of drugs of abuse

Trade/Proprietary Name:

Chemtron Biotech, Inc.'s Chemtrue® Single / Multi-panel Drug Screen Dip Card / Cassette Tests, contain 1 to 6 of the following DOA test(s) in each device:

1. Amphetamine test strip
2. Cocaine test strip
3. Marijuana (THC) test strip
4. Methamphetamine test strip
5. Opiates (Morphine) cut-off: 300ng/ml test strip
6. Phencyclidine test strip

Owner:

Ellen Liu
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8370 Juniper Creek Lane, #1-2
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Contact Person:

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Substantial Equivalency:

The Chemtrue® Single/Multi Drug Screen Test is substantially equivalent to other tests currently on the market.

Test Analyte	Predicate Device Name	Predicate Device 510(k) #
Amphetamine	ACON (INNOVACON) One Step Drug Screen Test Card	K020771
Cocaine	ACON (INNOVACON) One Step Drug Screen Test Card	K020771
Methamphetamine	ACON (INNOVACON) One Step Drug Screen Test Card	K020771
THC	ACON (INNOVACON) One Step Drug Screen Test Card	K020771
Opiates (Morphine)300	ACON (INNOVACON) One Step Drug Screen Test Card	K020771
PCP	ACON (INNOVACON) One Step Drug Screen Test Card	K020771

The predicate kit package insert is enclosed in ATTACHMENT A of this submission.

Proposed Labeling or Promotional Material for the Device:

Description of the device can be found in the attached proposed labeling, including an explanation of how the device functions, technical principle and concepts that form the basis for the device, as well as the physical and performance characteristics of the device, such as device design, materials used and physical properties. In accordance with FDA labeling requirements 21 CFR 809.10, enclosed are the draft copies of product labeling including copies of the technical product inserts. See ATTACHMENT B, C and D.

Intended Use

The Chemtrue® test device is intended for qualitative detection of drugs of abuse, for professional use, *in vitro* diagnostic use and for prescription use ONLY.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods.

Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

Technological Characteristics and Science Principles

The Drugs of Abuse (DOA) Screen Panels are one-step lateral flow immunoassays in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs that may

be present in urine. The test device consists of up to six test strips placed into separate panels of a plastic holder. On each test strip, a drug-protein conjugate is striped on the test band of the membrane - known as the test region (T) and the drug antibody-colloidal gold conjugate pads are placed at one end of the membrane (opposite in morphine). In the absence of drugs in the urine, the solution of the colored antibody-colloidal gold conjugates move along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drug-protein conjugate zones on the test band region. The colored antibody-gold conjugates then complexes with the drug-protein conjugates to form visible lines. Therefore, the formation of the visible precipitant in the test band occurs when the test urine is negative for the drug. If any drug is present in the urine, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. When a sufficient amount of drug is present in the urine, the drug will saturate the limited antibody binding sites and the colored antibody -colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, absence of the color band on the test region indicates a preliminary positive result.

A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line is manufactured as a built-in internal control of the test device and should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test cassette should be discarded. The presence of this colored band in the control region also serves 1) as verification that adequate specimen volume is added (flooding, if too much urine is added, or no flow, due to insufficient urine volume), 2) the test device IS properly functioning, and 3) as reagent control.

Summary of Device Similarities and Differences

Chemtron Biotech, Inc.'s Chemtrue® Single/Multi-panel Drug Screen Cassette and Dip Card tests are similar to other FDA-cleared devices for the qualitative detection of drugs of abuse tests: Amphetamine, Cocaine, Marijuana, Opiates, Methamphetamine and Phencyclidine test from other manufacturers such as ACON (Current INNOVACON), Branan Medical, etc. All of these products are based on the same technological characteristics, science principle and similar procedures. The similarities and differences between these tests are summarized as follows:

SIMILARITIES		
Item	Chemtrue® **Device**	**Predicate Kit**
Intended Use/Indications for use	Qualitative detection of drugs-of- abuse in urine for Professional, Prescription, *In Vitro*	Same

		Diagnostic Use Only	
Specimen		Urine	Same
Technological Characteristics and Principle		One-Step lateral flow competitive Immunoassay	Same
Device Design/ Performance	**Positive result**	1 colored line	Same
	Negative result	2 colored lines	Same
	Detection reagent	Colloidal gold	Same
	Accuracy Assessment	Confirm with GC/MS reference method	Same
Cut-off		Amphetamine 1000 ng/ml Methamphetamine 1000 ng/ml Cocaine 300 ng/ml Marijuana (THC) 50 ng/ml Phencyclidine 25 ng/ml Opiates(Morphine) 300 ng/ml	Same Same Same Same Same Same
Safety and Precaution		All urine specimens should be considered potentially hazardous and handled in the same manner as infectious agent.	Same
Read time		5 minutes	Same
Storage		2 – 30 °C (36 – 86°F)	Same

DIFFERENCES		
Item	Chemtrue® **Device**	**Predicate Kit**
Pre-treatment for urine specimen	Does not require pre-treatment for urine specimen. It is better than the Predicate kit.	Urine specimen needs to be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.
Time Frame of Result Stabilization	Do not read after 8 minutes.	Results remain stable for up to 4 hours after test initiation.

DISCUSSION AND CONCLUSION:

Based on the technological characteristics/principle, features of the device designs, test specimen matrix, test method and performance characterizations, as the set forth above, it can be concluded

that Chemtrue® Single/ Multi-panel Drug Screen tests are substantially equivalent to the predicate kit ACON's (INNOVACON) One Step Single and Multi Drug Screen test card product presently distributed commercially.

One of the advantages of the Chemtrue® Drug Screen Tests is no urine specimen pre-treatment, which is better than the Predicate kit, because it is much simple and convenience for the intended user(s).

With regarding to the result read time frame difference, since the device labeling clearly indicates the required "Read Time", it does not impact the result interpretation by the intended user(s). The device safety and effectiveness won't be affected either. For detailed discussion, refer to the section "Substantial Equivalence Discussion" of this submission.

Performance Data:

Chemtron Biotech, Inc. has reviewed the requirements of Section 514 of the Act, which states that to date no performance standards has been established for drug screen test systems by the FDA.

However, the studies listed in the notification are conducted according to "The Draft Guidance for Industry and FDA Staff" - " Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests, issued on: December 2, 2003", including the design of draft labeling and package inserts.

Chemtrue® Single / Multi-panel Drug Screen Cassette and Dip Card tests are one-step, lateral flow, colloidal gold based chromatographic immunoassays for the rapid, qualitative detection of Amphetamine, Methamphetamine, Marijuana (THC), Phencyclidine, Cocaine and Opiates (Morphine) 300 in human urine. It is intended for Professional, Prescription Use ONLY.

This assay provides a preliminary test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory result. Clinical and professional judgment must be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The product performance characteristics of Chemtrue® Single/Multi-panel Drug Screen cassette and Dip Card were evaluated with the confirmed GC/MS values in the blind-labeled clinical specimen correlation study. The results of these studies demonstrate Chemtrue® Single/ Multi-panel Drug Screen Test to be substantially equivalent to the performance characteristics of GC/MS methodology. Correlation studies, using clinical specimens, produced a > 98% total correlation when compared to the GC/MS methodology. Also the accuracy study data of Chemtrue® devices demonstrates the substantial equivalency to the data in the package insert of the predicate kit – ACON (INNOVACON) One Step Single and Multi Drug Screen test card.

Chemtrue® Single /Multi-Panel Drug Screening Tests *vs* GC/MS Value Analysis

Samples with drug concentration above the cut-off level were considered presumptive positive and concentration below the cut-off were considered negative.

Table 1. The data was summarized from method comparison (Accuracy) study against the GC/MS values of the clinical specimens

Test	Positive Agreement	Negative Agreement	Overall Agreement
AMP	57/57 = 100%	56/57 = 98.2%	113/114 = 99.1%
COC	61/61= 100%	54/54= 100%	115/115= 100%
OPI(MOR)300	55/56= 98.2%	62/63 = 98.4%	117/119 = 98.3%
MET	54/56 = 96.4%	50/50 = 100 %	104/106 = 98.1%%
PCP	52/52= 100%	62/62= 100%	114/114 = 100%
THC	56/56 = 100%	50/50= 100%	106/106= 100%

Conclusion:

Compared to the GC/MS values of clinical urine specimens (Total of 673 specimens), the results of the Accuracy (Method comparison) study demonstrate the substantial equivalency between the Chemtrue® Single/ Multi-Panel Drug Screen tests and the GC/MS reference method. It is also equivalent to the predicate kit, when compared to the data provided in the package insert of the predicate kit [ACON (INNOVACON) One Step Drug Screen test card]. The results demonstrated that Chemtrue® Single/ Multi-panel Drug Screen cassette and Dip card is safe and effective in detecting Amphetamine, Cocaine, Methamphetamine, Marijuana, Opiates (Morphine) 300 and Phencyclidine in human urine.

Other non-clinical performance data, such as analytical sensitivity (Cutoff characteristics), precision (Reproducibility), specificity (Cross-reactivity and interference) and stability studies are summarized in Section "Performance Characteristics", and the raw data is enclosed in ATTACHMENT E and ATTACHMENT G of this submission.

510(k) Summary was prepared By: Jane Zhang on August 3rd, 2010

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As required by 21 CFR 807.87(j))

I certify that in my capacity as QA/RA Director of Chemtron Biotech, Inc., I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____**(Signature),** _____ **(Date)**

Jane Zhang

Director of QA/RA, Chemtron Biotech, Inc.

FDA Official Correspondent

K_____

510(k) Number

Executive Summary

Description of the Device

Chemtrue® Single / Multi-panel Drug Screen Cassette and Dip Card tests are one-step, lateral flow, colloidal gold based chromatographic immunoassays for the rapid, qualitative detection of

Amphetamine, Methamphetamine, Marijuana (THC), Phencyclidine, Cocaine and Opiates (Morphine) 300 in human urine. It is intended for Professional /Prescription Use ONLY.

This assay provides a preliminary test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory result. Clinical and professional judgment must be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Concise Summary of Performance Testing:

1. Analytical Sensitivity Study Data

Control Level	No. of Tested	No. of Negative							No. of Preliminary
		AMP n=30	COC n=30	THC n=30	OPI300 n=30	MET n=30	PCP n=30	No. of Neg.	
0	180	30	30	30	30	30	30	**180**	**0**
-50% of the cutoff	180	30	30	30	30	30	30	**180**	**0**
-25% of the cutoff	180	30	30	30	30	29	29	**178**	**2**
Cut-off	180	18	16	17	16	15	14	**112**	**68**
+25% of the cutoff	180	1	4	3	1	2	1	**12**	**168**
+50% of the cutoff	180	0	0	0	0	0	0	**0**	**180**

Conclusion: The results support the claimed cut-off levels for each drug analyst. It also demonstrates that the performance of both Dip card and cassette product formats is consistent and equivalent.

2. Analytical Precision Study Data:

The precision study was conducted by three Operators with three batches per product format in replicates of 10 devices/lot at each control level of Negative, -50%, -25%, cut-off, +25% and +50% cutoff. The study was conducted in non-consecutive ten days using GC/MS confirmed commercial urine controls. The controls are blind coded according to a random table and evenly distributed to three operators. Every device was tested and interpreted by the same operator. The total of ten days run data is grouped into three sets: 3-day, 3-day and 4-day. A concise summary is in Table below:

AMP Test: Cutoff: 1000 ng/ml (Three lots were tested by three Operators)

Control Level	n	3-Day		3-Day		4-Day		TOAL	
		+	-	+	-	+	-	+	-
Negative	30	0	8	0	13	0	9	0	30
-50% of cutoff	30	0	12	0	5	0	13	0	30
-25% of cutoff	30	1	11	0	10	0	8	1	29

Cutoff	30	4	2	3	7	7	7	14	16
+25% of cutoff	30	7	0	8	1	13	1	28	2
+50% of cutoff	30	9	0	7	0	14	0	30	0

Cocaine Test: Cutoff: 300 ng/ml (Three lots were tested by three Operators)

Control Level	n	3-Day		3-Day		4-Day		TOAL	
		+	-	+	-	+	-	+	-
Negative	30	0	10	0	9	0	11	0	30
-50% of cutoff	30	0	11	0	8	0	11	0	30
-25% of cutoff	30	0	10	0	7	0	13	0	30
Cutoff	30	4	6	4	4	4	8	12	18
+25% of cutoff	30	3	0	13	1	10	3	26	4
+50% of cutoff	30	10	0	8	0	12	0	30	0

MAMP Test: Cutoff: 1000 ng/ml(Three lots were tested by three Operators)

Control Level	n	3-Day		3-Day		4-Day		TOAL	
		+	-	+	-	+	-	+	-
Negative	30	0	8	0	11	0	11	0	30
-50% of cutoff	30	0	11	0	8	0	11	0	30
-25% of cutoff	30	0	10	1	9	0	10	1	29
Cutoff	30	6	6	3	4	4	7	13	17
+25% of cutoff	30	6	0	7	0	16	1	29	1
+50% of cutoff	30	7	0	11	0	12	0	30	0

OPI (MOR) Test: Cutoff: 300 ng/ml (Three lots were tested by three Operators)

Control Level	n	3-Day		3-Day		4-Day		TOAL	
		+	-	+	-	+	-	+	-
Negative	30	0	11	0	7	0	12	0	30
-50% of cutoff	30	0	12	0	11	0	7	0	30
-25% of cutoff	30	0	4	0	8	1	17	1	29
Cutoff	30	5	6	3	2	7	7	15	15
+25% of cutoff	30	7	1	11	0	10	1	28	2
+50% of cutoff	30	8	0	12	0	10	0	30	0

PCP Test: Cutoff: 25 ng/ml (Three lots were tested by three Operators)

Control Level	n	3-Day		3-Day		4-Day		TOAL	
		+	-	+	-	+	-	+	-
Negative	30	0	8	0	9	0	13	0	30
-50% of cutoff	30	0	13	0	7	0	10	0	30
-25% of cutoff	30	0	9	0	10	0	11	0	30

Cutoff	30	4	7	7	4	3	5	14	16
+25% of cutoff	30	8	1	7	0	14	0	29	1
+50% of cutoff	30	5	0	10	0	16	0	30	0

THC Test: Cutoff: 50 ng/ml (Three lots were tested by three Operators)

Control Level	n	3-Day		3-Day		4-Day		TOAL	
		+	-	+	-	+	-	+	-
Negative	30	0	3	0	10	0	17	0	30
-50% of cutoff	30	0	7	0	12	0	11	0	30
-25% of cutoff	30	0	9	0	6	0	15	0	30
Cutoff	30	3	7	4	2	5	9	12	18
+25% of cutoff	30	13	1	12	1	2	1	27	3
+50% of cutoff	30	11	0	7	0	12	0	30	0

The study raw data are enclosed in the ATTACHMENT E for reference.

Conclusion: The results of the reproducibility study demonstrate that the Chemtrue® Drug Screen tests are able to produce consistent results from lot-to-lot, Operator-to-Operator and day-to-day runs, during the repeated assays and measurements. It also demonstrates an equivalent assay performance between Dip Card and Cassette formats

3. Analytical Accuracy Study: The accuracy of the Chemtrue Drug Screen Test device was evaluated with the confirmed GC/MS values in the blind-labeled clinical specimen correlation study (a total of 673 clinical specimens). The results of these studies demonstrate Chemtrue® Single/ Multi-panel Drug Screen Test to be substantially equivalent to the performance characteristics of GC/MS methodology. Correlation studies, using clinical specimens, produced a > 98% total correlation when compared to the GC/MS methodology. Also the accuracy study data of Chemtrue® devices demonstrates the substantial equivalency to the data in the package insert of the predicate kit – ACON (INNOVACON) One Step Single and Multi Drug Screen test card. For details, refer to the "Method comparison (Accuracy) study, section Performance Characteristics" of this submission.
4. Analytical Specificity Study: The data is summarized in Section "Performance Characteristics, Specificity" and the raw data is enclosed in ATTACHMENT E of this submission.
5. Stability study: Three lots of each product format: Dip Card and Cassette were included in the stability study, and accelerated stability at 60°C and 40°C data supported two years shelf-life of the products. Accelerated 40°C and real-time stability studies are still on-going. The copy of the raw data is enclosed in ATTACHMENT G.

Substantial Equivalency:

Chemtron Biotech, Inc.'s Chemtrue® Single/Multi-panel Drug Screen Cassette and Dip Card tests are similar to other FDA-cleared devices for the qualitative detection of drugs of abuse tests: Amphetamine, Cocaine, Marijuana, Opiates, Methamphetamine and Phencyclidine test from other manufacturers such as ACON (Current INNOVACON), Branan Medical, etc. All of these products are based on the same principle, same technological characteristics and similar procedures.

Device Comparison:

Product Attribute	Chemtrue® Drug Screen Tests	Predicate Kit	Substantially Equivalent
Analytes	Amphetamine, Cocaine, Methamphetamine, Opiates (MOR), PCP and THC	Amphetamine, Cocaine, Methamphetamine, Opiates (MOR/MOP) and THC, as well as six other drug analytes	Yes
Intended Use	Qualitative detection of drugs-of-abuse in urine	Qualitative detection of drugs-of-abuse in urine	Yes
Specimen Type	urine	urine	Yes
Assay Methodology	Lateral flow immunochromato-graphic assay	Lateral flow immunochromato-graphic assay	Yes
Assay Cut-off	Amphetamine 1000ng/mL Cocaine 300ng/mL Methamphetamine 1000ng/mL OPI (MOR) 300 ng/mL PCP 25 ng/mL THC 50ng/mL	Amphetamine 1000ng/mL Cocaine 300ng/mL Methamphetamine 1000ng/mL OPI (MOR) 300 ng/mL PCP 25 ng/mL THC 50ng/mL	Yes
Time to read	5 minutes	5 minutes	Yes
Indications of Use	Prescription	Prescription	Yes
Analytical Accuracy	>96%	>90%	Yes

DIFFERENCES		
Attribute	**Chemtrue® Device**	**Predicate Kit**
Pre-treatment for urine specimen	Does not require pre-treatment for urine specimen. It is better than the Predicate kit.	Urine specimen needs to be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.
Time Frame of Result Stabilization	Do not read after 8 minutes.	Results remain stable for up to 4 hours after test initiation.

DISCUSSION AND CONCLUSION:

Based on the technological characteristics/principle, features of the device designs, test specimen matrix, test method and performance characterizations, as the set forth above, it can be concluded that Chemtrue® Single/ Multi-panel Drug Screen tests are substantially equivalent to the predicate

kit ACON's (INNOVACON) One Step Single and Multi Drug Screen test card product presently distributed commercially.

The difference of the read time claims between Chemtrue® device and the predicate kit does not impact the result interpretation by the intended user(s), since the device labeling clearly indicates the required "Read Time". The device safety and effectiveness won't be affected either. For details, refer to the section "Substantial Equivalence Discussion" of this submission.

Proposed Labeling

1. Package Labeling - Copies of the final draft package labeling for the Chemtron Biotech, Inc.'s Chemtrue® Single/ Multi-panel Drug Screen Cassette and Dip Card tests are in Attachment B and C. It is our intention that final package labeling will be substantially similar to the draft labeling attached.

2. Package Insert – A copy of the final draft package insert is enclosed in ATTACHMENT D. The final package insert will be substantially similar to that enclosed.

3. Promotional Material - Promotional material and advertising materials, when prepared, will be consistent with the product package insert and this 510(k) pre-market notification submission.

Summarized By: Jane Zhang

Date: August 3rd, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Chemtron Biotech, Inc.
c/o Jane Zhang
Official FDA Correspondent
8370 Juniper Creek Lane Suite 1-2
San Diego, CA 92126

JAN 20 2011

Re: k102203
Trade/Device Name: Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: II
Product Code: DKZ, DIO, DJC, DNK, LCM, LDJ
Dated: January 10, 2011
Received: January 10, 2011

Dear Ms. Zhang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k102203

Device Name: Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests

Indications for Use:

The Chemtron Biotech, Inc.'s Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card Tests are rapid chromatographic immunoassays for the qualitative detection of up to six of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration
Amphetamine	AMP	d-Amphetamine	1000 ng/ml
Cocaine	COC	Benzoylecgonine	300 ng/ml
Marijuana	THC	11-nor-Δ^9-THC9-COOH	50 ng/ml
Methamphetamine	MET	d-Methamphetamine	1000 ng/ml
Opiates	OPI/MOR	Morphine	300 ng/ml
Phencyclidine	PCP	Phencyclidine	25 ng/ml

The Chemtrue® Single/Multi-Panel Drug Screen Cassette and Dip Card are intended for qualitative detection of drugs of abuse for health care professionals, *in vitro* diagnostic use and prescription use ONLY. It is not intended for point-of-care settings or over the counter use.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods.

Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety